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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/980,614

04/17/2002

Yi Li

60020-5001-US

8325

23973

7590

10/03/2006

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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/980,614	Applicant(s) LI ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date, _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the amendment filed 07/31/2006.

The previous rejection under 35 USC 103(a) is withdrawn in view of applicant's remarks.

The following rejection is a new rejection of the claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Azizi et al.

Azizi et al disclose transplantation of human marrow stromal cells and astrocyte precursors (neurospheres) (see Abstract; page 3910, Results). The transplanted cells behaved like endogenous CNS stem cells (see Migration of Implanted Cells, page 3911). Finally, Azizi et al suggest the use of the transplant in the treatment of various disease. Azizi et al teaches the administration of the same cells, by the same route, to the same organ, and said cells migrate in the same way as claimed in the instant

application. Azizi et al further provide the suggestion to use said implants in the treatment of various CNS diseases. While Azizi et al does indeed use a healthy brain, the mechanism of action of these migrated cells is an inherent property of these cells, not the condition of the brain. They would function in the same way regardless of the condition of the brain. Azizi et al does indeed show, survival, engraftment, and migration of these stromal cells. While Azizi et al also deliver their cells to a healthy CNS, there is no showing that delivery to damaged or diseased tissue would function any differently. Further, there is a clear suggestion to treat CNS diseases by Azizi et al. It is agreed that Azizi et al do not teach that the transplanted cells would differentiate into parenchymal cells in the brain. However, the evidence presented by the Azizi et al paper indicates that these transplanted cells do indeed become differentiated once they are transplanted given that they are said to behave like endogenous CNS cells. The process of differentiation of these cells is therefore inherent once the cells are isolated, transplanted and migration takes place. Indeed, this migration appears to be evidence of differentiation. The instant claims are therefore anticipated by Azizi et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 11/027,881 (US'881). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'881 claims a method of treating a mammal by isolating stromal cells from bone marrow, and administering the cells (claim 1). The disease may be considered an injury, and may be in the brain of the mammal (see claims 7 and 8). Administration may be intravascular, intracerebral, intravenous, or intraarterial (see claim 16). Processes which follow the administration of the same cells by the same route, and for the treatment of similar CNS injury or disease would therefore be obvious to one of ordinary skill in the art. Reduction of axonal loss, induction of angiogenesis, induction of neurogenesis, induction of synaptogenesis, reduction in demyelination, and reduction in axonal injury are all

secondary to the implantation of the same cells, by the same method. Given that claims of copending US'881 clearly set out the same method of treatment, administration, same cells cultured and implanted, as well as the same migration, those of ordinary skill would have further expected similar therapeutic treatment of CNS disorders. As such, the instant claims would have been obvious to one of ordinary skill in the art at the time of invention given the claims of US'881.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 11/431,290 (US'290). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'290 claims a method of treating a mammal by isolating stromal cells from bone marrow, and administering the cells (claim 1). The disease may be considered an injury, and may be in the brain of the mammal (see claims 5 and 6). Administration may be intravascular, intracerebral, intravenous, or intraarterial (see claim 9). Given the cells differentiate and behave like endogenous cells, those of ordinary skill would have expected no immune response to the stromal cells. Further, given the blood-brain barrier, those of ordinary skill would have also expected no immune response. Given that claims of copending US'290 clearly set out the same method of treatment, administration, same cells cultured and implanted, as well as the same migration, those of ordinary skill would

have further expected similar therapeutic treatment of CNS disorders. As such, the instant claims would have been obvious to one of ordinary skill in the art at the time of invention given the claims of US'290.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

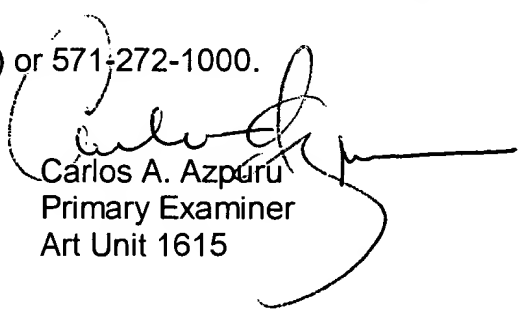
Kohyama et al (Differentiation 68(4-5):235-244, October 2001) is cited as evidence that the differentiation of these transplanted cells does indeed take place.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpuru
Primary Examiner
Art Unit 1615

ca